SECTION 5: 510(k) SUMMARY

K072552
p. 1 of 2

SUBMITTER: Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095

CONTACT: William D. Jordan

DATE PREPARED: September 7, 2007

DEC 14 2007

TRADE OR PROPRIETARY NAME: Guide Wire Torque Device

CLASSIFICATION NAME: Wire, Guide, Catheter, 870.1330

PREDICATE DEVICES: MYSHELL, Alligatork Torque Device, K040498

DEVICE DESCRIPTION:

The Guide Wire Torque Device is a guide wire accessory developed to assist in the manipulation and placement of hydrophilic and other typical guide wires during interventional procedures. It accomodates guide wires from .018 to .038 inches and is composed of three components: 1. An ABS plastic body; 2. A polypropylene "core" which grips the guide wire; and 3. A stainless steel spring which supplies the force to grip the guide wire.

The design of the Guide Wire Torque device allows single-handed operation. The wire gripping actuator is depressed while the guide wire is threaded through the device's lumen. When the Guide Wire Torque Device is located on the guide wire in the appropriate location, the actuator is released alllowing the device to grip the guide wire.

INTENDED USE:

The Guide Wire Torque Device is intended to facilitate guide wire manipulation during interventional procedures.

TECHNOLOGICAL CHARACTERISTICS:

All of the component materials found in the Guide Wire Torque Device have been used in legally marketed Merit devices and were found safe for use. The Guide Wire Torque Device has been evaluated and passed appropriate biocompatibility testing for Cytotoxicity. Both the Guide Wire Torque Device and the predicate are mechanically similar. Both use a tension spring mechanism to provide a grip on the guide wire.

Merit believes that the prior use of the component materials of the Guide Wire Torque Device in legally marketed devices, the performance data provided, and the biocompatibility data provided demonstrate that the Guide Wire Torque Device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2007

Merit Medical Systems, Inc.
c/o Mr. William D. Jordan
Senior Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, UT 84095

Re: K072552
Trade/Device Name: Guide Wire Torque Device
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 12, 2007
Received: November 14, 2007

Dear Mr. Jordan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

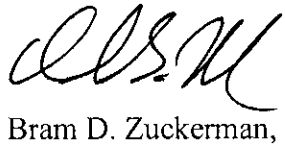
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K072552

Device Name: Guide Wire Torque Device

Indications for Use:

The Guide Wire Torque Device is intended to facilitate guide wire manipulation during interventional procedures.

Prescription Use __X__	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072552